OMB NO. 0990-0115

SOLICITATION

SECTION A – SOLICITATION/CONTRACT FORM

1. Purchase Authority: FAR 1.602-1

2. Request For Proposals (RFP) Number:	**2. Issue Date:**	**3. Just in Time:**	**5. Set Aside:**
NIH-NIAMS-BAA-05-01	January 14, 2005	___ NO _X_ YES See Part IV, Section L	_X_ NO ___ YES

6. TITLE: Innovative Therapies for Rheumatic and Skin Diseases

7. ISSUED BY:
National Institutes of Health
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Contracts Management Branch
Democracy One, Suite 800, MSC 4872
6701 Democracy Boulevard
Bethesda, Maryland 20892-4872

8. SUBMIT OFFERORS TO:
The address noted in Item #7 to the left
(Also see instructions under Packaging and Delivery of Proposals, SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS, SECTION L.1)

9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the location specified above, and in the number of copies specified in Section L.1., GENERAL INFORMATION, paragraph (a), until **4:30 p.m. (local time), March 25, 2005**. Offers must be valid for 120 days. Please specify this period on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043." If your proposal is not received by the Contracting Officer or his/her designee at the place and by the time specified above, then it will be considered late and handled in accordance with HHSAR Clause 352.215-70, entitled "LATE PROPOSALS AND REVISIONS," located in SECTION L.1. of this solicitation.

10. Offeror must provide full name, address, TIN, and if different, the address to which payment should be mailed. In addition, the Offeror must provide an electronic address (e-mail), along with a facsimile address.

11. FOR INFORMATION CALL: Lisa Hill, Contract Specialist
PHONE: 301-594-2543
E-MAIL: hilll1@mail.nih.gov
COLLECT CALLS WILL NOT BE ACCEPTED.

12. Table of Contents on following page.

NOTE: Offerors are responsible for routinely checking both the FedBizOpps website and the NIAMS Contracts Management Branch's website. Solicitation amendments, if any, will be posted at the FedBiz Opps website (http://www.fedbizopps.gov) and the NIAMS Contracts Management Branch's web site (http://www.niams.nih.gov/rtac/funding/grants/rfp/wwwrfp.htm). Individual notifications will not be provided.

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PART I - THE SCHEDULE

A. BROAD AGENCY ANNOUNCEMENT DESCRIPTION

You are invited to submit a proposal in accordance with the requirements of this Broad Agency Announcement (BAA) NIH-NIAMS-BAA-05-01 entitled "Innovative Therapies for Rheumatic and Skin Diseases." The Broad Agency Announcement is authorized by FAR 6.102 and further described in FAR 35.106. A BAA is a general announcement of an agency's research interest and constitutes a solicitation. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research areas identified by the Government.

A proposal submitted in response to this BAA must present a detailed technical and cost proposal designed to meet the Research and Technical Objectives described in this announcement. The proposal must be signed by an official authorized to contractually commit the submitting organization.

The Statement of Work, including the specific work requirements and performance specifications, is developed and defined by the Offeror, not the Government.

Proposals are not evaluated against a specific Government need, as in the case of a conventional Request for Proposals (RFP), since they are not submitted in accordance with a common Statement of Work issued by the Government. Instead, Research and Technical Objectives are provided in the BAA that describe the research areas in which the Government is interested. Proposals received as a result of the BAA are evaluated by a peer review group also know as the Scientific Evaluation Panel (SEP) in accordance with the Evaluation Criteria specified in SECTION M, EVALUATION FACTORS FOR AWARD, of the BAA. All of the competing proposals are ranked on the basis of their respective relevance and scientific merit. The score assigned by the SEP is considered the final score. An Order of Merit Ranking is established by the Contracting Officer in lieu of a Competitive Range.

Negotiations are conducted with those offerors selected from the Order of Merit Ranking based on their scientific merit and those specific considerations set forth in the solicitation under SECTION M of the BAA (i.e., availability of funds, scientific priority, and program balance). During negotiations, there is an opportunity to refine the proposed Statement of Work in consultation with the Project Officer and Contracting Officer. At the conclusion of negotiations, those offerors selected from the Order of Merit Ranking are allowed the opportunity to submit a Final Proposal Revision (FPR) to address weaknesses in the proposal, based on issues identified by the SEP and to revise costs as may be appropriate.

The NIAMS anticipates awarding 2 contract awards. Awards are expected to be made on or about September 30, 2005. The NIAMS estimates that the average annual total cost (direct and indirect cost combined) for these contracts is $250,000 to $1,200,000 per contract. However, it is anticipated that the total cost for each award may very depending upon the scope of the project and the technical objectives of the award. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. Please note, however, that in no event shall the period of performance exceed 5 years.

The resultant award document will be tailored to the final negotiations with the selected offeror(s), as appropriate, for the type of contractor organization, cost and/or fee arrangements, and other elements as negotiated with the offeror prior to award.

B. BACKGROUND

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports research aimed at discovering the causes of skin and rheumatic diseases and at developing new treatments for the prevention and cure of these diseases. Numerous new pharmacologic and biologic therapeutic approaches are now feasible in diseases such as lupus, rheumatoid arthritis, and psoriasis. Some of the new therapies are being used for more common conditions such as cancer and transplantation, but trials for less common conditions such as lupus or scleroderma are not yet planned. Others are in the very early stages of development, for example, angiogenesis inhibitors, transcription factor inhibitors, protein kinase inhibitors, gene therapy, anticytokine oligonucleotides, and bone marrow transplantation (stem cell rescue).

The goal of the Broad Agency Announcement (BAA) is to accelerate the application of new drugs, biologics, and other nonbehavioral interventions for the short- and long-term management of symptoms, signs, and systemic and structural changes in patients with established rheumatic and skin diseases and for the development of strategies for prevention of disease onset, disease progression, or structural damage to target organs in patients at high risk. New and emerging agents for the treatment of lupus, rheumatoid arthritis, scleroderma, myositis, Sjogren's syndrome, and other rheumatic diseases are included. In the skin diseases area, inflammatory, autoimmune, and genetic skin diseases are included as are small trials for innovative therapies on wound healing.

Therapies could be targeted to any of the processes/components of the pathogenesis of the diseases. They include, but are not limited to, therapies that:

1. Suppress or inhibit systemic or organ-specific inflammatory processes that cause damage to the skin or organs involved in rheumatic disease.

2. Modulate, suppress, or eliminate specific autoimmune responses and other relevant immune mechanisms involved in skin and rheumatic diseases, rather than those that are broadly immunosuppressive.

3. Promote healing and repair of injured tissues, organs and chronic skin wounds, limited to translational research ready for human use, not basic research into disease process.

4. Modify hereditary skin diseases with a significant chronic wounds component that are amenable to improvement by gene therapy.

Open-labeled, Phase I and III trials are included under this solicitation. The trials should be designed so that the preliminary data obtained would be sufficient to design the next phase (Phase II/III), for which the investigators will have to seek separate funding. The proposals will be required to include evaluation of clinical and or laboratory parameters to establish the basis for understanding the potential mechanism of action of the tested therapy. Also appropriate will be proposals that include an initial phase (no more than 12 months) to complete preclinical testing of highly promising products/approaches. Phase III-like studies likely to change standard of care are included under this BAA for rare diseases when it is apparent that large-scale traditional phase III trials are not feasible.

Through the development and conduct of these clinical trials, the NIAMS expects to foster collaborations and partnerships between academics and biotechnology and pharmaceutical companies. Although it is anticipated that the research will be conducted at academic institutions primarily, some of the biologics, drugs, and other products and agents to be tested may have been under research and development in the biotechnology and pharmaceutical companies. Collaborative arrangements are thus encouraged under this BAA.

TECHNICAL OBJECTIVES

TECHNICAL OBJECTIVE A. To design, develop, and carry out pilot/feasibility (open- label, Phase I/II) clinical studies to establish the safety and gather enough preliminary evidence of efficacy of new and innovative therapeutic approaches to rheumatic and skin diseases. *[NOTE TO THE OFFERORS:]*

1. *The approach is to be selected by the offeror. The intervention may be intended to be used as a single-treatment agent, as an adjuvant to existing therapies, or as a combination therapy of known agents. The purpose of the therapy may include treatment of clinical manifestations of established disease, delay in disease progression, or prevention of organ/system involvement. The specific aims of the trial must be clearly and concisely presented. These should include a clear specification of the primary and major secondary endpoints to be measured with a clear differentiation of the importance of various endpoints.*

2. *The proposal should include a background and significance section that describes the scientific and medical rationale to test the selected approach, as well as the potential advantages and/or additional benefits to be obtained by the use of such new approaches. The significance of the proposed clinical trial, how the trial will test the hypothesis proposed, and how the results will advance our knowledge of theory and practice in this area must be clearly stated.*

3. *Preliminary Studies. A summary of the studies that lead to the proposed clinical trial should be presented. Data from preclinical studies, other applications/uses of the proposed approach, and pilot studies that show the need for such a*

trial or the feasibility of the trial should also be presented, if available. For feasibility studies, supporting data from other research should be included so that the approach chosen is clearly justified.

4. *Draft Protocol. The proposal must include a draft protocol that meets the specific aims set by the offeror for the clinical trial. The experimental design should describe the methodology to be used, including the following:*
   a. *A plan overview and description of trial design (screening, baseline, number of visits, laboratory tests, etc). Rescue medication/treatments for treatment failures should be described.*

   b. *Plans to recruit and coordinate activities, training, reporting, etc., with other Clinical Centers, if a multicenter trial is proposed. The proposal shall include a description of strengths and capabilities, including expertise in relevant clinical studies and participation in similar clinical trials, for each Clinical Center. Letters of commitment and cooperation must be provided.*
   c. *Overall recruitment strategies with a description of pitfalls, competing trials, and alternative options. The National Institutes of Health policy requires that women and members of minority groups and their subpopulations and children be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This issue must be addressed in your proposal (see Section L.2. of the RFP for further information and guidance).*

   d. *Patient inclusion and exclusion criteria, and definitions of disease severity or other entry criteria.*

   e. *Description of study agents including rationale for the selection of agent dose and duration of treatment. Arrangements made with suppliers for obtaining the appropriate formulation of the agents should be described. If a drug manufacturer has agreed to provide the drug at no cost, a copy of the agreement must be included with the proposal for review and approval by the Government. Food and Drug Administration regulatory issues related to study agents may be handled during Phase I of the trial (see timetable below)*

   .f. *Selection and discussion of instruments to measure primary and secondary outcomes.*

   g. *Plans to monitor potential toxicities.*

   h. *Copies of all available data-collection forms, informed-consent forms, study instruments and questionnaires, and a schedule of clinic visits and patient assessments.*

   i. *Randomization strategy, if appropriate.*

   j. *Sample size calculations, estimates of attrition, and rationale for the selection of methods to conduct analysis of endpoints. The technical proposal must include a thorough description of sample calculation and detail the assumptions made.]*

TECHNICAL OBJECTIVE B. To design and implement basic or clinical research ancillary projects linked to the clinical trial protocol.

[NOTE TO THE OFFERORS: The ancillary studies should be designed to take advantage of the clinical trial setting proposed (Technical Objective A of this solicitation) to answer a hypothesis- driven question related to disease pathogenesis, response to treatment, or the mechanisms of action of the study agent(s). Clinical studies related to disease characterization, identification of surrogate endpoints, or identification of disease biomarkers are also included. The proposal should be organized to include specific aims, background and significance, technical approach, and bibliography. It should not exceed 10 pages. Ancillary studies can be conducted by the investigators directly involved in the study or by others under collaborative arrangements. Multiple ancillary studies may be proposed. The Government reserves the right to approve/disapprove any or all ancillary studies proposed by the offeror.]

The estimated timetable for the study follows:

1. **Phase I - Planning** (4 to 6 months in duration)

   a. Within 45 days after contract award, meet with NIAMS staff to discuss the specific activities and the deliverables that will be required during Phase I.

b. Refine and finalize the Study Protocol. Develop a Manual of Operations (MOP) for the conduct of the trial. Obtain Project Officer review and approval of the MOP. Finalize patient forms and questionnaires after obtaining Project Officer review and approval.

c. Provide to the local Institutional Review Board, Data Safety Monitoring Board (DSMB), and the Government the final study protocol for review and approval.

d. Prior to beginning enrollment of patients, the Government must obtain clearance from the Office of Management and Budget or a clinical exemption, whichever is appropriate. To assist in obtaining this clearance, the Contractor shall provide to the Project Officer verification of Institutional Review Board approval and copies of informed consent forms, patient questionnaires, informational brochures and/or advertisements, etc.

e. **The Contractor shall not begin work on Phase II activity until written approval has been received from the Contracting Officer.**

f. Provide staff to coordinate the conduct of the study as outlined in the Study Protocol and Manual of Operations. The final Study Protocol and final Manual of Operations as well as all Government-approved revisions to those documents shall automatically be incorporated as part of the Statement of Work.

g. Prepare training materials for the investigators who will be conducting the study and hold training sessions.

h. Assume responsibility for developing, pretesting, reproducing, and distributing appropriate reporting forms.

i. Develop administrative procedures necessary for reimbursement of Clinical Centers for clinical operating expenses and accepted data forms. Investigators will be reimbursed for clinical operating expenses and will receive a fixed unit price for each completed and accepted patient randomized data form and another for each completed and accepted patient followup data form.

[*NOTE TO OFFERORS: Reimbursement to Clinical Centers for limited operating costs and fixed unit prices for data forms will be negotiated as the basis for reimbursement and payment under the contract. Included in operating costs might be a small percentage of time for the Principal Investigator and the Research Nurse for the overall operation of the clinic, travel costs to attend Steering Committee meetings, and other costs associated with operations. A fixed unit price will be established for all data deliverables. Included in the fixed unit price would be costs associated with the tests to be performed on each patient, and patient incentives such as reimbursement for travel or parking. Please note that patient test costs are normally not subject to indirect costs. Routine patient care costs are to be assumed by third party or other normal payment procedures.]*

2. **Phase II - Recruitment/Enrollment and Followup** (18 to 24 months in duration)

a. Randomly assign patients to treatment groups and monitor patient recruitment.

b. Assume responsibility for prompt accumulation, entry, and editing of study data.

c. Communicate with the Clinical Centers concerning missing, delayed, incomplete, or erroneous data.

d. Submit Monthly Recruitment/Enrollment Reports including the Inclusion of Women and Minorities in Research Report.

e. Prepare and submit Quarterly Performance Reports to monitor study progress, quality of data, clinical investigator performance (enrollment, protocol compliance, dropout rates, form completion), complications, and adverse events.

f. Arrange for meetings as needed in Phase II. Record, produce, and distribute minutes for all meetings and conference calls.

g. Prepare reports on patient recruitment, status of data collection, quality control, and matters relating to any other data to be discussed at the Steering Committee and DSMB meetings or conference calls, if appropriate.

3. **Phase III - Analysis** (6 to 12 months in duration)

   a. Finalize data collection from Clinical Centers.

   b. Continue analysis of study data.

   c. Work with Clinical Centers in the preparation of reports and scientific manuscripts.

   d. Prepare a final data tape for delivery to the NIAMS 1 month prior to contract completion date.

   e. Prepare and submit the Final Report and other study documentation to the NIAMS on or before the last day of the contract.

E. REPORTING REQUIREMENTS

Performance and Technical Progress Reports will be submitted by the Contractor as follows:

Draft Manual of Operations: A draft Manual of Operations, which includes the protocol, shall be submitted to the Project Officer for review and approval within three months of contract initiation. This manual shall be updated and distributed as necessary during the conduct of the study.

Monthly Recruitment/Enrollment and Safety Reports (MRES): During recruitment and enrollment, the Contractor shall provide monthly reports that outline the number of patients screened and enrolled during the reporting period, including separate tables with data on the inclusion of women and minorities in the research study. In addition, a second report shall be submitted that delineates the monthly and cumulative total number of adverse events and serious adverse events. The first MRES report shall cover the first 30 days of enrollment and shall be due 10 days after the end of the reporting period. Thereafter, reports shall be due on or before the 10th calendar day following each reporting period. Once enrollment is completed, the Contractor must notify the Contracting Officer, and the requirement for submission of the monthly report will no longer be required. One copy of the monthly report shall be submitted to the Project Officer and one copy shall be submitted to the Contracting Officer.

Semi-Annual Progress Report: Concordant with the meetings of the Data Safety Monitoring Board (DSMB), the Contractor shall submit Semi-Annual Progress Reports, and as needed during the study, to allow for the monitoring of study progress, quality of data, clinical investigator performance (enrollment, protocol compliance, form completion), complications, and adverse events. At a minimum, this report shall include 1) qualitative and quantitative descriptions of overall progress; 2) a list of any current problems that may impede performance, and proposed corrective actions with a time frame for these actions; 3) a discussion of the work to be performed during the next reporting period; and 4) an action items list. The first report will cover the first full six months of performance and shall be due April 30, 2006. Thereafter, reports shall be due on or before the 30th calendar day following each reporting period or concordant with the meeting of the DSMB as agreed upon by the Contracting Officer and Contractor. This report shall be submitted via the internet in MS Word or WordPerfect format. One copy of the semi-annual report shall be submitted to the Project Officer and one copy shall be submitted to the Contracting Officer.

Annual Technical Progress Report for Clinical Research Study Populations: The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of the resulting contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report. The Contractor shall submit the report in accordance with ARTICLE F.1. DELIVERIES in the subsequent contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies.

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly

encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

The first report shall be due on or before October 29, 2006. Thereafter, the report shall be due on or before the 30th calendar day following each reporting period. This final "Annual Technical Progress for Clinical Research Study Populations" report shall be due and submitted with the Final Report (discussed below) which is due on or before the last day of the contract. One copy of the report shall be submitted to the Project Officer and one copy shall be submitted to the Contracting Officer.

Final Report: This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. One copy of the Final report shall be submitted to the Project Officer and one copy shall be submitted to the Contracting Officer. A Semi-annual report will not be required for the period when the Final Report is due.

Summary of Salient Results: The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. One copy shall be submitted to the Project Officer and one copy shall be submitted to the Contracting Officer.

Optional Form 310, Protection of Human Subjects Assurance/Certification/Declaration: This form or its equivalent shall be submitted to the Contracting Officer to document the Contractor's (or Subcontractor's if applicable) Institutional Review Board annual review of the project or in the event they have reviewed and approved changes to the study or consent forms.

Distribution of Reports: The Contractor shall send copies of each report as specified below: Project Officer - 1 copy; Contracting Officer - 1 copy

4. DELIVERABLES SCHEDULE

The Contractor will be required to deliver the reports outlined in the Reporting Requirements section of the contract in accordance with the following Schedule of Deliverables:

Item	Description	Quantity	Delivery Schedule
a.	Manual of Operations	1 to the P.O.	Draft due within 3 months of contract initiation and updates as needed
b.	Monthly Recruitment/Enrollment and Safety Report (MRES)	1 to the C.O. 1 to the P.O.	10 days following each reporting period
c.	Semi-Annual Report	1 to the P.O. 1 to the C.O.	30 days after the end of the reporting period or concordant with the DSMB meetings
d.	Annual Technical Progress Report for Clinical Research Study Populations	1 to the P.O. 1 to the C.O.	30 days following the anniversary date of the contract
e.	Final Report & Summary of Salient Results	1 to the P.O. 1 to the C.O.	On or before the expiration date of the contract
f.	OF-310, Protection of Human Subjects Assurance/ Certification/Declaration	1 to the P.O. 1 to the C.O.	As needed

PART I - THE SCHEDULE – (continued)

SECTIONS B – H – UNIFORM CONTRACT FORMAT – GENERAL

The contract schedule as set forth in sections B through H (see **http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm**) is NOT an exact representation of the contract that will result from this RFP. Rather, it is an example that provides general information pertinent to many of the contracts awarded and should be reviewed as such. Specific contractual provisions pertinent to the offeror (i.e., those relating to the organizational structure [e.g., non-profit, commercial] and specific cost authorizations unique to the offeror's proposal and requiring contracting officer prior approval) will be discussed in the negotiation process and will be included in the resultant contract. This example contract is meant to provide the offeror with an overview of the elements of a typical contract.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

SPECIAL NOTE FOR SOLICITATION PURPOSES: This SECTION I contains listings of clauses which may be applicable to most contracts resulting from this RFP. However, the organizational structure of the successful offerors(s) will determine the specific general clauses listing to be contained in the contract(s) awarded from this RFP.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS AND MODIFICATIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations. It is expected that the following clause(s) will be made part of the resultant contract:

ALTERNATE IV (OCTOBER 1997) of FAR Clause 52.215-21, **REQUIREMENTS FOR COST OR PRICING DATA OR INFORMATION OTHER THAN COST OR PRICING DATA--MODIFICATIONS** (OCTOBER 1997) is added.

FAR Clause 52.216-7, ALLOWABLE COST AND PAYMENT (DECEMBER 2002), is modified in paragraph (a) to delete the words "subpart 31.2 of the Federal Acquisition Regulation (FAR)" and substitute "45 CFR part 74, Appendix E". *[Applies to Hospitals, including both profit and non-profit]*.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/contractor shall be determined at the time of award. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER I) CLAUSES

FAR 52.219-4, Notice Of Price Evaluation Preference For HubZone Small Business Concerns (OCTOBER 2004).

"(c) Waiver of evaluation preference…..

[ ] Offeror elects to waive the evaluation preference."

FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (JUNE 2003), is applicable to this solicitation as follows:

"(b) Evaluation adjustment. (1) The Contracting Officer will evaluate offers by adding a factor of [*Contracting Officer insert the percentage*] percent to the price of all offers, except--...".

Offerors will be evaluated by adding a factor of ***[insert %]*** to the price of all offers, except offers from disadvantaged business concerns that have not waived the adjustment.

Alternate I (JUNE 2003), is applicable to this contract.

FAR 52.227-14, Rights in Data - General (JUNE 1987)

ALTERNATE IV (JUNE 1987), FAR 52.227-14, Rights in Data – General (JUNE 1987) *[Applies to Colleges and Universities only]*.

ALTERNATE V (JUNE 1987), FAR 52.227-14, Rights in Data – General (JUNE 1987). Specific data items that are not subject to paragraph (j) include: *personal patient information and identifiers.*

FAR Clause 52.227-16, Additional Data Requirements (JUNE 1987), is applicable to this solicitation.

[NOTE TO OFFERORS: One or several of the following clauses pertaining to Cost Accounting Standards may be included in the resultant contract:]

******* (USE IN NEGOTIATED CONTRACTS OVER $500,000 – FOR FULL CAS COVERAGE [EXCEPT Small Businesses, Educational Institutions and Foreign Contractors – SEE EXCEPTIONS AT 48 CFR CHAPTER 99 [APPENDIX B, FAR LOOSELEAF EDITION], SUBPART 9903.201-1) ***

FAR 52.230-2, Cost Accounting Standards (APRIL 1998).

*** (USE BELOW IN NEGOTIATED CONTRACTS OVER $500,000 BUT LESS THAN $25 MILLION, AND THE OFFEROR CERTIFIES THAT IT IS ELIGIBLE FOR AND ELECTS TO USE MODIFIED CAS COVERAGE, EXCEPT Small Businesses, Educational Institutions, and Foreign Contractors – SEE EXCEPTIONS AT 48 CFR CHAPTER 99 [APPENDIX B, FAR LOOSELEAF EDICTION], SUBPART 9903.201.1) ***

FAR 52.230-3, Disclosure and Consistency of Cost Accounting Practices (APRIL 1998).

*** (USE BELOW IN NEGOTIATED CONTRACTS THAT ARE EXEMPT FROM CAS REQUIREMENTS SOLELY ON THE BASIS THAT THE CONTRACT IS TO BE AWARDED TO A UNITED KINDGOM CONTRACTOR AND IS TO BE PERFORMED SUBSTANTIALLY IN THE UNITED KINGDOM – SEE 48 CFR CHAPTER 99 [APPENDIX B, FAR LOOSELEAF EDITION], SUBPART 9903.201-1(B)(2)) ***

FAR 52.230-4, Consistency in Cost Accounting Practices (AUGUST 1992).

*** (USE BELOW IN NEGOTIATED CONTRACTS AND SUBCONTRACTS AWARDED TO EDUCATIONAL INSTITUTIONS, WHEN THE CONTRACTOR OR SUBCONTRACT PRICE EXCEEDS $500,000, UNLESS THE CONTRACT IS EXEMPTED (SEE 48 CFR CHAPTER 99, 9903.201-1), THIS CONTRACT IS TO BE PERFORMED BY AN FFRDC (SEE 9903.201-2 (c)(5), OR THE PROVISION AT 9903.201-2(c)(6)(FAR APPENDIX B) APPLIES.) ***

FAR 52.203-5, Cost Accounting Standards – Educational Institution (APRIL 1998).

*** (USE BELOW IN NEGOTIATED CONTRACTS THAT CONTAIN EITHER THE FORMER FAR CLAUSE 52.230-2, 52,230-3, OR 52.230-5.) ***

FAR 52.230-6, Administration of Cost Accounting Standards (APRIL 1996).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION / PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR/PHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR 352.223-70, Safety and Health (JANUARY 2001)
HHSAR 352.224-70, Confidentiality of Information (APRIL 1984).
HHSAR 352.270-8, Protection of Human Subjects (JANUARY 2001).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES

NIH (RC)-7 Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).
NIH (RC)-11, Research Patient Care Costs (APRIL 1984).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.244-6, Subcontracts for Commercial Items and Commercial Components (APRIL 2003)

a. **Definition**.

Commercial item, as used in this clause, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, as used in this clause, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

b. To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

c. Notwithstanding any other clause of this contract, the Contractor is not required to include any FAR provision or clause, other than those listed below to the extent they are applicable and as may be required to establish the reasonableness of prices under Part 15, in a subcontract at any tier for commercial items or commercial components:

1. 52.219-8, Utilization of Small Business (15 U.S.C. 637(d)(2) and (3)
2. 52.222-26, Equal Opportunity (E.O. 11246);
3. 52.222-35, Affirmative Action for Special Disabled and Vietnam Era Veterans (38 U.S.C. 4212(a));
4. 52.222-36, Affirmative Action for Handicapped Workers (29 U.S.C. 793);
5. 52.222-39, Notification of Employee Rights Concerning Payment of Union Dues or Fees (E.O 13201) and
6. 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (46 U.S.C. 1241)

d. The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III - LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents or exhibits are either attached or are available on line at http://www.niaid.nih.gov/contract/ref.htm and are incorporated in this RFP:

THE FOLLOWING FORM MUST BE COMPLETED AND SUBMITTED PRIOR TO THE SUBMISSION OF YOUR PROPOSAL BY NO LATER THAN APRIL 15, 2005.

1. Attachment 1 - Proposal Intent Response Sheet, 1 page (attached).
2. Attachment 2 – Privacy Act System of Records, 1 page (attached).

THE FOLLOWING FORMS MUST BE COMPLETED AND SUBMITTED WITH EACH TECHNICAL PROPOSAL: (A copy of each form shall be included with the original and every copy of the technical proposal, these documents are available at: http://www.niaid.nih.gov/contract/ref.htm).

3. Government Notice for Handling Proposals
4. Technical Proposal Cost Summary
5. Summary of Related Activities,
6. Targeted/Planned Enrollment Table, 01 (Mod. By OAMP 10/2001),
7. Protection of Human Subjects Assurance Identification/IRB Certification/Declaration, OMB No. 0990-0263 (formerly Optional Form 310).

THE FOLLOWING FORMS MUST BE COMPLETED AND SUBMITTED WITH EACH BUSINESS PROPOSAL (available on-line at http://www.niaid.nih.gov/contract/ref.htm):

8. NIH-2043, Proposal Summary and Data Record.
9. Breakdown of Proposed Estimated Cost (Plus Fee).
10. SF-LLL, Disclosure of Lobbying Activities.
11. Small Business Subcontracting Plan Format.
12. Small Disadvantaged Business (SDB) Participation Plan.
13. Offeror's Points of Contact.

THE FOLLOWING FORMS WILL BE ATTACHED TO ANY CONTRACT RESULTING FROM THIS RFP:

14. NIH (RC)-7, Procurement of Certain Equipment, (OMB Bulletin 81-16).
15. NIH (RC)-4, Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts.
16. NIH (RC)-11, Research Patient Care Costs.
17. NIH 2706, Financial Report of Individual Project/Contract, with instructions.
18. Safety and Health, HHSAR Clause 352.223-70.
19. Inclusion Enrollment Report.
20. Disclosure of Lobbing Activities

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

Annual Representations and Certifications (FAR 52.204-8, January 2005)
Prospective Contractors shall complete electronic annual Representations and Certifications at http://orca.bpn.gov in conjunction with the required registration in the Central Contractor Registration (CCR) database (see FAR 4.1102).

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **PACKAGING AND DELIVERY OF PROPOSAL**

Your proposal shall be organized as specified in SECTION L.2., INSTRUCTIONS TO OFFERORS.

Proposals for furnishing the supplies and/or services in the SCHEDULE will be accepted at the location specified in (3) below, and in the number of copies specified in (1) below, until 4:30 p.m. (local time), **March 25, 2005**. Delivery and marking of proposals shall be as indicated below:

1. Number of Copies: The number of copies required of each part of your proposal are as follows:

   Technical Proposal: Original plus 10 copies
   Business Proposal: Original plus 4 copies

2. External Package Marking

   In addition to the address cited below, the outside of each package should be marked with the following information:

   RFP No. NIH-NIAMS-BAA-05-01

3. Address

TO: **If using U.S. Postal Service:**
Contracting Officer
Contracts Management Branch, EP
National Institute of Arthritis and
Musculoskeletal and Skin Diseases, NIH
6701 Democracy Boulevard
Suite 800, MSC 4872
Bethesda, Maryland 20892-4872

If hand delivered or delivery service:
Contracting Officer
Contracts Management Branch, EP
National Institute of Arthritis and
Musculoskeletal and Skin Diseases, NIH
6701 Democracy Boulevard, Suite 800
Bethesda, Maryland 20817

b. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (January 2004)]**

(a) *Definitions*. As used in this provision--

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time*," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.* (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be

submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--
  (i) The solicitation number;
  (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
  (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
  (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
  (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.
  (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

    (*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
    (*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
    (*3*) It is the only proposal received.

  (B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

  (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
  (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
  (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
(ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.
(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.
(iv) A summary of the rationale for award;
(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

(End of Provision)

c. **"JUST IN TIME"**

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

Small Business Subcontracting Plan. A subcontracting plan will **not** be submitted with the initial business proposal but must be submitted upon request from the Contracting Officer, after initial evaluation of proposals.

Cost/Pricing Information. The offeror's business proposal shall include the basic cost/pricing information specified in SECTION L2. of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. *[NOTE: The information may also include submission of cost or pricing data.]*

d. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.
(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

e. **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

f. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that multiple awards will be made from this solicitation and that awards may be made on/about September 30, 2005.

It is anticipated that the award from this solicitation will be a multiple-year, cost reimbursement type completion contract, with a term of three (3) years, and that incremental funding will be used for this contract **.**

g. **ESTIMATE OF EFFORT**

It is expected that a cost-reimbursement type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government estimates that the total cost (direct and indirect) will range from $300,000 to $500,000 per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

h. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition. Any other commitment, either explicit or implied, is invalid.

i. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

j. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

k. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. The relative importance of the award selection factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the offeror whose proposal provides the best overall value to the Government, cost and other factors considered.

l. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

m. **SERVICE OF PROTEST - FAR 52.233-2 (AUGUST 1996)**

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Contracts Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
Bethesda, Maryland 20892-6500

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

n. **LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70**

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) Contract Type and General Clauses

It is contemplated that a cost reimbursement type contract will be awarded. Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Section L1. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm (120 days minimum) and the designation of those personnel authorized to conduct negotiations. (See Section J, entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and labor-categories, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated [See Attachment entitled, Technical Proposal Cost Summary)]. However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified and separate cost estimates provided.

(6) Evaluation of Proposals

The Government will evaluate technical proposals in accordance with the criteria set forth in, SECTION M, of this RFP.

(7) Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) Standards for Privacy of Individually Identifiable Health Information

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information about the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements, and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

(10) Privacy Act – Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

-to the cognizant audit agency and the General Accounting Office for auditing.

-to the Department of Justice as required for litigation.

-to respond to congressional inquiries.

-to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(11) Selection of Offerors

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review panel. The panel will evaluate each technical proposal in strict conformity with the technical evaluation criteria of the RFP, utilizing point scores and written critiques. The panel may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business proposal will be subjected to a cost realism and/or cost/price analysis.

c) If award is made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government has communication and/or conducts discussions prior to awarding a contract-

(1) Based on the written recommendations of the technical review committee/peer review group/source evaluation panel, the Contracting Officer will, in concert with program staff, establish an ORDER OF MERIT RANKING. This ranking will be based upon the scientific merit of the proposed research, the relevance to the technical objectives outlined in this solicitation, and program/scientific priority.

Oral or written discussions will be conducted with offerors whose proposals are the most meritorious, relevant, and of highest priority to the program area. All aspects of the proposal are subject to discussion, including cost, technical approach, and contractual terms and conditions. At the conclusion of discussions, each offeror still being considered for awards hall be given an opportunity to submit a written Final Proposal Revisions (FPR) with the reservation of the right to conduct limited negations to finalize details of the award with the selected source in accordance with HHSAR 315.670.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the

results of the technical evaluation, evaluation of cost and any and all other award selection factors specified in Section M.

f) The NIAMS reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAMS' requirements. Synopses of awards exceeding $25,000 will be published on the FedBizOpps website.

(12) Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment 8 to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small Businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service-Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Businesses, Small Disadvantaged Businesses, Women-Owned Small Businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service-Disabled Veteran-Owned Small Businesses and that each such aspect of the offeror's plan will be judged independent of the other.

(6)The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged , Women-Owned, HubZone, Veteran-Owned, and Service-Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged , Women-Owned, HubZone, Veteran-Owned, and Service-Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged , Women-Owned, HubZone, Veteran-Owned, and Service-Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with : Small, Small Disadvantaged , Women-Owned, HubZone, Veteran-Owned, and Service-Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged , Women-Owned, HubZone, Veteran-Owned, and Service-Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged , Women-Owned, HubZone, Veteran-Owned, and Service-Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan in SECTION J.

(13) HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS.

(14) Extent of Small Disadvantaged Business Participation

In accordance with FAR part 15.304(c)4, the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for

construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under Section M shall be used for evaluating SDB participation under this RFP. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment must clearly stated in your proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size/ The Department of Commerce website for the annual determination is: http://www.arnet.gov/References/sdbadjustments.htm.

Offerors shall **provide in one clearly marked section of the Business Proposal,** SDB participation targets, expressed as dollars and percentages of total contract value, in each authorized NAICS Industry Subsector(s), as may be applicable. The applicable NAICS Code for this requirement is 541710, as specified in Section L.1 (d). A total target for SDB participation by the prime contractor, including joint ventures and team arrangements*, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **SDB Participation Plan information may be provided in one the format prescribed below or in a format developed by the offeror.**

If the SDB evaluation factor in Section M includes a subfactor that considers the extent to which SDB concerns must be specifically identified in the participation plan, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute for submission of the subcontracting plan**, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE
Targets for SDB Participation – NAICS Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value - $1,000,000	25%	$250,000
SDB Participation by Prime (includes joint venture partners and team arrangements)*	10%	$100,000
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(15) Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from

multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(16) Salary Rate Limitation in Fiscal Year 2005

Offerors are advised that pursuant to P.L. 108-447, Title II, General Provisions, Section 204, no NIH Fiscal Year 2005 (October 1, 2004 - September 30, 2005) funds may be used to pay the direct salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses), also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 108-447, Title II, General Provisions, Section 204, applies only to Fiscal Year 2005 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-447, Title II, General Provisions, Section 204, states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health and the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of the Executive Level I."

Link to Executive Schedule Salaries: http://www.opm.gov/oca/PAYRATES/index.htm

***NOTE TO OFFERORS**: The current Fiscal Year Executive Level I salary should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the terms of the Fiscal Year 2005 appropriation legislation regarding salary rates.*

(17) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

(1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

(2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

(3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

(4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.**

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

i) public disclosure of significant financial interests;
ii) monitoring of research by independent reviewers;
iii) modification of the research plan;

iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
v) divestiture of significant financial interests; or
vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(18) ROTC Access and Federal Military Recruiting on Campus

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) the either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions the have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining toe students (who are 17 years of age or older) enrolled at the covered educational entity.

(19) Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating produce development. Intellectual property restrictions can stifle the broad dissemination of the new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the p [public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf .

(20) Electronic and Information Technology Accessibility

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L. 105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR Part 1194) require that all EIT acquired must ensure that:

1. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

2. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

(21) **Sharing Research Data**

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site: http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.

(22) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

(a) Submission of Offers in the English Language, FAR 52.214-34, (April 1991)
(b) Submission of Offers in U.S. Currency, FAR 52.214-35, (April 1991)
(c) Facsimile Proposals, FAR 52.215-5 (October 1997)
(d) Facilities Capital Cost of Money, FAR 52.215-16 (October 1997)
(e) Order of Precedence-Uniform Contract Format, FAR 52.215-8 (October 1997)
(f) Preaward On-Site Equal Opportunity Compliance Evaluation (Over $10,000,000) FAR 52.222-24 (February 1999)
(g) Identification of Uncompensated Overtime, FAR 52.237-10 (October 1997)

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks. **Please note that there is a page limitation of 30 pages for the Technical Proposal (see item (2) Technical Proposal Table of Contents/Format below).**

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

1) Objectives/ Specific Aims. State clearly and concisely the overall goals and specific aims of the proposed project. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere.

2) Background and Significance. Review pertinent already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it. Describe the scientific rationale for the selection of the targeted therapy selected. Indicate the significance of the proposed study to advance current approaches for the evaluation of the selected therapy and relation to comparable work in progress elsewhere. Discuss the innovative technological and conceptual aspects of this project.

3) Technical Approach. Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Describe the technical approach corresponding to each of the Technical Objectives/Specific Aims presented in TECHNICAL DISCUSSIONS, paragraph a, Statement of Work, subparagraph 1., Objectives/Specific Aims. Include a description of preliminary data, if available. Discuss the scientific rationale, feasibility, expected results and alternatives for each of the approaches selected. Include description of statistical approaches when appropriate. If the study involves human subjects, include a description of the plan to include women, minorities, and children in the study population. When collaborative approaches with existing organizations and networks are proposed, include letters of commitment.

4) Methods. Describe the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

5) Schedule. Provide a schedule for completion of the work and delivery of items specified in the Statement of Work or Article F.2., Deliveries, Part I, Schedule. Performance or delivery schedules should be indicated for phases or segments, as applicable, as well as for the overall program. Schedules should be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

i) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

ii) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss their qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

iii) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity must be indicated and the anticipated sources must be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.
-Their availability to the project and the amount of time anticipated.
-Willingness to act as a consultant.
-How rights to publications and patents will be handled.

iv) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

v) Summary of Related Activities

Offerors must complete the Summary of Related Activities form included as Attachment 5. This form should indicate all other support for the principal investigator/project director (and other key personnel named in the proposal) in direct support of their research endeavors. Other support is defined as any project specific funds or resources, whether Federal, non-Federal or institutional, available to the principal investigator/project director (and other key personnel named in the proposal) in direct support of their research endeavors through research or training grants, cooperative agreements, contracts, fellowships, gifts, prizes, and other means. For prizes and gifts, include only those that support the specific project.

Information regarding active or pending sources of support available to the principal investigator/project director (and other key personnel named in the proposal), whether related to this proposal or not, is an important part of the review and award process and must be included in the proposal. Please follow carefully the instructions on the Summary of Related Activities attachment in providing this information.

vi) Institutional Experience and Facilities

Describe organizational and administrative structure of the proposed program and institutional commitment to the program.

Describe the facilities and resources, plans for study coordination, data management and analysis, as well as the availability of computers and other equipment for performance of the proposed project.

(2) **Technical Proposal Table of Contents/Format**
(NOTE: Instructions to offerors are included in parentheses or as footnotes.)

a. Technical Proposal Cover Sheet…….……Page 1

b. Technical Proposal Table of Contents ……..….Page 2

c. Summary of Objectives and Methods (Abstract)*……..Page 3

d. Lay Language Summary…….Page 4

e. Technical Plan (Refer to Technical Proposal Instructions indicated above).

It is recommended that the Technical Plan section be limited to only 30 pages, excluding references. Also, see notes indicated with asterisks below.

(1) SCOPE OF WORK
- (a) Objectives/Specific Aims……Page 5
- (b) Background and Significance ……Page
- (c) Technical Approach ……Page
- (d) Methods ……..Page
- (e) Schedule ……..Page

(2) PERSONNEL (List by name, title, department and organization, and detail each person's qualifications and role in the project).

Provide narrative for:

- (a) Principal Investigator/Project Director
- (b) Other Investigators
- (c) Additional Personnel (e.g., technical support, subcontractors, consultants)

{NOTE: For key personnel, include 2 page biosketch/resume and the form entitled "Summary of Related Activities" included in Part III, Section, J.]

(3) FACILITIES/RESOURCES and DIRECT COSTS (Complete and submit Technical Proposal Cost Summary located in Section J and you should list/describe all equipment, facilities and other resources available for this project; and floor plan of laboratory/clinical space).

(4) OTHER CONSIDERATIONS (Complete and submit the Summary of Labor and Direct Costs (Technical Proposal) located in Section J and provide brief narrative of any unique arrangements, safety procedures in place, human subject and minority and gender issues, animal welfare issues, etc.).

f. OTHER SUPPORT (A Summary of Related Activities" form must be provided for all Key Personnel; this form is located in PART III, Section J).

g. HUMAN SUBJECTS

h. LITERATURE CITED

i. APPENDICES (resumes, protocol, policy manuals, etc., for above Technical Plan; list each Appendix; Appendices must be clear and legible and easily located.)

* State the proposal's broad, long-term objectives and specific aims. Describe concisely the research design and methods for achieving these goals. DO NOT EXCEED ONE PAGE in providing the abstract. Identify the RFP Number, institution, and Principal Investigator on the abstract.

**The front side of a page equals one page. The front and back of a page equals two pages.

***Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch.

(3) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Section M).

(4) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(5) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

IMPORTANT NOTE TO OFFERORS: The following paragraphs(6 through 16) shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled "HUMAN SUBJECTS."

(6) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)

a) Copies of the Department of Health and Human services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through interventions or interaction with the individual, or identifiable private information. The regulation extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1 – 6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of the research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt

category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*, (telephone: 301-496-7014*), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR* an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR* and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

**Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at http://www.hhs.gov/ohrp/ . Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html*

(7) **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the

contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(8) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and//or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. This site may be downloaded at no cost and modified for the use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and completion of this program will satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution has already developed educational

programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and /or conduct of the research under the contract, the contractor shall provide the following written information to the contracting officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

(9) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is the policy of the NIH that women and members of minority groups and their sub-population must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusions is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (section 492B of Public Law 103-43), **and applies to research subjects of all ages**.

All investigator proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research" (http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals
This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studies in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studies, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.
The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table" (see Section J, Attachments)

NOTE: For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table" in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: http://www.whitehouse.gov/omb/fedreg/ombdir15.html

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**[1] require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions – Significant Difference), by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and /or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support not negate significant differences in intervention effect between subgroups.

Use the form in Section J, Attachments, entitled "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J – List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

[1]See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, for the Definition of an "NIH-defined Phase III clinical trial."

(10) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethnical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (section 101 (b) and 410 (b) of

45 GFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:
http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors may also obtain copies from contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of : (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justification for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.
- There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
- A separate, age-specific study in children is warranted and preferable. Examples include:
    - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
    - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
    - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
    - Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
    - Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
    - Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of Children

For the purposes of this solicitation, a child is defined as an individual under the age of 21 years. The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and verifying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec. 401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(11) **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:
http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offferors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusion of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials . A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual / Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB – required for multi-site trials)
- Institutional Review Board (IRB) (required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(12) **Research Involving Human Fetal Tissue**

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g-2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

(13) **Research Involving Prisoners as Subjects**

a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS-funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.pdf

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:
   a) to describe the prevalence or incidence of a disease by identifying all cases, or
   b) to study potential risk factor associations for a disease, and

2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2-7) and determined and documented that:
   a) the research presents no more than minimal risk, and
   b) no more than inconvenience to the prisoner-subjects, and
   c) prisoners are not a particular focus of the research.

For more information about this Waiver see http://www.hhs.gov/ohrp/special/prisoners/Prisoner%20waiver%206-20-03.pdf

(14) **Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1).

The NIH Guidelines for Research Involving Recombinant DNA Molecules (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html) and any subsequent revisions to the Guide Notice) stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the NIH Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and//or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the project officer and contracting officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of NIH funding for any work related to Recombinant DNA Research or a requirement for the contracting officer's prior approval of any or all Recombinant DNA projects under any contract awarded from this solicitation. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the project officer and contracting fficer. (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)

(15) **Human Embryonic Germ Cell (HEGC) Research**

1. Guidelines.
   Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/news/newsArchive/fr25au00-136.asp) and (http://stemcells.nih.gov/news/newsArchives/fr14no01-95.asp) (only the information regarding human embryonicgerm cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice NOT-OD-02-049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

   All offerors should read the "NIH Guidelines:" (http://stemcells.nih.gov/news/newsArchives/fr25au00-136.asp) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

   Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

   If, in response to the solicitation, the offeror proposes to use human embryonic germ cells, it must submit, as a separate attachment to its proposal, an original and two copies of the documentation and assurances that address the areas covered in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html). Prior to any award made under this

solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.bof the NIH Guidelines. Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles," http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-044.html)

(16) **Human Embryonic Stem Cell (HESC) Research**

On August 9, 2001, the President announced the criteria that must be met for Federal funds to be used for research on existing human embryonic stem cell lines. These criteria were subsequently published by the NIH at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html.

The following eligibility criteria must be met:

1. The derivation process (which commences with the removal of the inner cell mass from the blastocyst) must have already been initiated prior to August 9, 2001;
2. Prior to August 9, 2001, the embryo from which the stem cell line was derived no longer had the possibility of development as a human being;
3. The stem cells must have been derived from an embryo that was created for reproductive purposes;
4. The embryo was no longer needed for these purposes;
5. Informed consent must have been obtained for the donation of the embryo;
6. No financial inducements were provided for the donation of the embryo.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry (Athe NIH Registry") that lists the human embryonic stem cells that meet the eligibility criteria. This registry is available at: http://stemcells.nih.gov/registry/.

Research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal funding.

If a particular human embryonic stem cell line has not been required by the Statement of Work, an offeror proposing research involving human embryonic stem cells must cite a human embryonic stem cell line that is listed in the NIH Registry in its proposal.

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee and profit.

(2) **Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

(1) Solicitation, contract, and/or modification number;
(2) Name and address of Offeror;
(3) Name and telephone number of point of contact;
(4) Name, address, and telephone number of Contract Administration Office, (if available);
(5) Name, address, and telephone number of Audit Office (if available);
(6) Proposed cost and/or price; profit or fee (as applicable); and total;

(7) The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the Contracting Officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
(8) Date of submission; and
(9) Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) **Information Other than Cost or Pricing Data**

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**
Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**
Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**
Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**
Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**
Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**
Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**
If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**
Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**
List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

(4) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include—

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.C.3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(End of provision)

(5) **Total Compensation Plan - Instructions**

*******This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.C. of this RFP. *******

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors INCLUDED IN THE COMPETITIVE RANGE WILL BE REQUIRED TO SUBMIT a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(6) **Total Compensation Plan - Evaluation**

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(7) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(8) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

c) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)**

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and(j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

a. It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled "Limitation of Funds." Under that clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover an initial period of performance. Additional funds are intended to be allotted from time to time, to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

b. The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Clauses. (End of Provision)

f) **FAR 52.215-16, Facilities Capital Cost of Money (June 2003)**
(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(a)(2) are met. One of the allowability criteria requires that the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money. (End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

__ The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

__ The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(9) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).
b) What priority the work will be given and how it will relate to other work.
c) The amount of time and facilities available to this project.
d) Information on their cognizant field audit offices.
e) How rights to publications and patents are to be handled.
f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in

Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(10) **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

For solicitations using "Just in Time" procedures, only those offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(11) **Representations and Certifications**

Prospective contractors shall complete electronic annual representations and certifications via the Online Representations and Certifications Application (ORCA), a part of the Business Partner Network (BPN), at http://orca.bpn.gov in conjunction with required registration in the Central Contractor Registration (CCR) database (see FAR 4.1102). Prospective contractors shall update the representations and certifications submitted to ORCA as necessary, but at least annually, to ensure they are kept current, accurate, and complete. The representations and certifications are effective until one year from date of submission or update to ORCA.

(12) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state. Only those offerors included in the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

The major evaluation factors for this solicitation include technical (which encompasses experience), cost/price factors, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price factors and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make awards to those offerors whose proposals provide the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the Request for Proposals (RFP). The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below. Offerors are advised to pay particular attention to providing the information requested in the "NOTES TO OFFERORS" in order to assist the reviewers in evaluating proposals.

If a proposal is received from a foreign organization or involves a foreign component, the peer review group will address the need or appropriateness of accomplishing the work outside the United States.

The estimated cost of an offer must be reasonable for the tasks to be performed and, in accordance with FAR 15.305, will be subject to a cost realism analysis by the Government.

All technical proposals will undergo evaluation by a peer-review group also known as the Source Evaluation Panel (SEP). The final stage of the evaluation is the establishment of an ORDER OF MERIT RANKING in which all competing proposals are ranked on the basis of their respective relevance and scientific merit evaluations. Subsequent awards depend upon the availability of funds, scientific priority, and program balance that the NIAMS determines to exist at the time of the award selection.

2. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH policy requires:

a. **Protection of Human Subjects from Research Risks**
The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIAMS that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal and provide a narrative with regard to four issues: Risks to Human Subjects: Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L of this solicitation for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects), or "acceptable."

If your discussion regarding the protection of human subjects from research risks is rated "unacceptable" and your proposal is being considered for award, you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussion, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

b. **Data and Safety Monitoring**
The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, in general for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the specific requirements of this solicitation for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable."

If the information provided regarding Data and Safety Monitoring is rated "unacceptable" and your proposal is being considered for award, you will be afforded the opportunity to further discuss and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered "unacceptable," your proposal may not be considered further for award.

c. **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, **OR**

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), **OR**

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

-

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will address the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

    - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
    - overriding factors dictate selection of subjects); or
    - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

    - inclusion of those groups would be inappropriate with respect to their health,;or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.

- For NIH-defined Phase III clinical trials, reviewers will also address whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion.

If the information you provide in your proposal regarding the inclusion of women and minorities is rated "unacceptable" and your proposal is being considered for award, you will be afforded the opportunity to further discuss, clarify, or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion/exclusion of women/minorities is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

d. **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' narrative evaluation of the offeror's response to this evaluation criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable."

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and your proposal is being considered for award, you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

3. **EVALUATION OF OPTIONS**

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

4. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and your proposal is considered for award, you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

5. **EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH**

The offeror's proposal must address the plans for sharing model organisms, OR state appropriate reasons why such sharing is restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Section L should be addressed.

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and your proposal is considered for award, you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award.

6. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

A. **SCIENTIFIC AND TECHNICAL MERIT** **65 Points**

1. The clinical and biological relevance and the innovation of the interventions (20 points)

2. The documented adequacy, feasibility, and scientific and technical merit of the proposed methods and approaches (including all requirements itemized in the Research and Technical Objectives section) to meet the research objectives under Research Areas A or B. (25 points)

3. Suitability of the proposed plan for randomization of patients, calculation of sample data management, and the data analysis plan. (10 points).

4. Adequacy of the proposed methods of coordination, monitoring, and central management of all activities required by the study protocol, including procedures, coordination of data collection, and specialized tests. (10 points).

B. **PERSONNEL AND EXPERIENCE** **25 Points**

1. Documented training, experience, expertise, and availability of the Principal Investigator necessary for planning and directing the proposed studies. (15 points)

2. Documented training, experience, and availability of all personnel in conducting the proposed technical procedures. (10 points)

C. **INSTITUTIONAL EXPERIENCE AND FACILITIES** **10 Points**

1. Adequacy of the organizational and administrative structure of the proposed program and institutional commitment to the program. (5 points)

2. Availability and adequacy of the facilities and resources necessary for conducting study coordination, data management and analysis, including computer hardware, software, and other equipment in order to successfully implement the requirements of the contract. (5 points)

TOTAL **100 Points**

7. **PAST PERFORMANCE EVALUATION**

Past performance is not considered to be appropriate for evaluation in this acquisition. Because of the innovative nature of work required by the RFP, the FAR requirement of evaluating an offeror's past performance information is waived for this project. Past performance, however, will be considered when determining Contractor responsibility using the information required by the "Qualifications of the Offeror" portion of Section L of the solicitation.

8. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be reviewed or scored by SEP, but the Government's conclusions about overall commitment and realism of the offeror's SDB participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business participation targets will be evaluated before determination of the order of merit ranking. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform. Offers will be evaluated on the following subfactors:

(a) The extent to which SDB concerns are specifically identified;
(b) The extent of commitment to use SDB concerns;
(c) The complexity and variety of the work SDB concerns are to perform;
(d) The realism of the proposal;
(e) The past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation; and
(f) The extent of participation of SDB concerns in terms of the value of the total acquisition.

ATTACHMENT 1 - PROPOSAL INTENT RESPONSE SHEET

RFP No. NIH-NIAMS-BAA-05-01

PLEASE REVIEW THE ATTACHED REQUEST FOR PROPOSAL. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY **FEBRUARY 18, 2005**. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.

==========

TITLE AND BRIEF DESCRIPTION OF PROJECT:

Company/Institution:

Company/Institution Address:

Principal Investigator Name and Title:

Telephone No. and Email Address:

Names of Collaborating Institutions and Investigators (including consultants and subcontractors):

[ ] DO INTEND TO SUBMIT A PROPOSAL

[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

==========

RETURN TO:

Eileen Webster-Cissel, Contracting Officer
National Institutes of Health
National Institute of Arthritis and Musculoskeletal
and Skin Diseases
Contracts Management Branch
Democracy One, Suite 800, MSC 4872
6701 Democracy Boulevard
Bethesda, Maryland 20892-4872
FAX NO: (301)480-5996
EMAIL: hilll1@mail.nih.gov

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this solicitation.

ATTACHMENT 2 - PRIVACY ACT SYSTEM OF RECORDS

Federal Register: April 7, 1997 (Volume 62, Number 66)
Notices, Pages 16596_16602

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Privacy Act of 1974; New System of Records
agency: National Institutes of Health, HHS.
action: Notification of a new system of records.

Summary: In accordance with the requirements of the Privacy Act, the National Institutes of Health (NIH) is publishing a notice of a new system of records, 09_25_0200, ``Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD." This system notice serves as an umbrella system for most NIH clinical, epidemiologic and biometric research studies. Thirty-eight existing NIH system notices were subsumed under this notice (listed in the system notice under System Manager(s)), to reduce the number and avoid future proliferation of like system notices. We are also proposing routine uses for this new system; with two exceptions, these routine uses were already contained in the preceding system notices. The first new routine use will allow disclosure to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions. The purpose of the disclosure is to plan for or provide such services, bill or collect third-party reimbursements. The second new routine use will allow disclosure for the purpose of reporting child, elder, or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

Dates: NIH invites interested parties to submit comments on the proposed internal and routine uses on or before May 7, 1997. NIH has sent a report of a New System to the Congress and to the Office of Management and Budget (OMB) on November 6, 1996. This system of records will be effective 40 days from the date of publication unless NIH receives comments on the routine uses which would result in a contrary determination.

Address: Please submit comments to: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075, 301- 496-2832.

Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday. for further information contact: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075, 301-496- 2832.

The numbers listed above are not toll free.

Supplementary information: The National Institutes of Health (NIH) proposes to establish a new system of records: 09-25-0200, ``Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD." This umbrella system of records will be used by NIH staff to document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities. This inclusive system notice will achieve agency administrative efficiencies, avoiding confusion created by the current fragmented pool of Institute, Center and Division (ICD) system notices. Because of its unique organizational structure, NIH has, over the recent decades, experienced a proliferation of almost identical system notices that differ only by disease/disorder under study or ICD interest. This system notice subsumes thirty-eight existing system notices and will offer coverage for research not currently covered by an appropriate system notice. The consolidation of similar research systems of records into one generic-type notice will also serve the public interest. It will alleviate burden on the public associated with multiple attempts at notification, access and correction of record information when individuals are not sure which research system notice applied to their study participation.

The system will comprise records about individuals as relevant to a articular research study. Examples include, but are not limited to: Name, study identification number, address, relevant telephone numbers, Social Security Number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curriculum vitae); and associated correspondence. The amount of information recorded on each individual will be only that which is necessary to accomplish the purpose of the system.

The records in this system will be maintained in a secure manner compatible with their content and use. NIH and contractor staff will be required to adhere to the provisions of the Privacy Act and the HHS Privacy Act Regulations. The System Manager will control access to the data. Only authorized users whose official duties require the use of such information will have regular access to the records in this system. Authorized users are HHS employees, and contractors responsible for implementing the research.

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and videotapes. Manual and computerized records will be maintained in accordance with the standards of Chapter 45-13 of the HHS General Administration Manual, ``Safeguarding Records Contained in Systems of Records,'' supplementary Chapter PHS hf: 45-13, the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31). Data on computer files is accessed by keyword known only to authorized users. Access to information is thus limited to those with a need to know. Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel. Researchers authorized to conduct research on biological specimens will typically access to the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual. All authorized users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Depending upon the sensitivity of the information in the record, additional safeguard measures are employed.

The routine uses proposed for this system are compatible with the stated purposes of the system. The first routine use permits disclosure of a record for an authorized research purpose under specified conditions. The second routine use permitting disclosure to a congressional office is proposed to allow subject individuals to obtain assistance from their representatives in Congress, should they so desire. Such disclosure would be made only pursuant to a request of the individual. The third routine use allows disclosure to the Department of Justice for use in litigation. The fourth routine use allows disclosure of records to contractor, grantee, experts, consultants or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. The fifth routine use allows disclosure to certain relevant third parties (e.g., relatives, prior employees, Motor Vehicle Administration, State vita statistics offices) when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. The sixth routine use allows disclosure to tumor registries for maintenance of health statistics. The seventh routine use allows the PHS to inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, or to disclose such information to State or local public health departments under specified circumstances. The eighth routine use allows disclosure of certain diseases and conditions, including infectious diseases, to appropriate representatives of State or Federal Government as required by State or Federal law. The ninth routine use allows records to be disclosed to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements. The tenth routine use allows disclosure to organizations deemed qualified by the Secretary, DHHS, to carry out quality assessment, medical audits or utilization reviews. The eleventh routine use allows information to be

disclosed for the purpose of reporting child, elder or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

The following notice is written in the present, rather than future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system has become effective. Dated: October 30, 1996.
Anthony L. Itteilag,
Deputy Director for Management, National Institutes of Health. 09-25-0200

SYSTEM NAME:Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD.

SECURITY CLASSIFICATION:None.

SYSTEM LOCATION: Records are located at NIH and Contractor research facilities which collect or provide research data for this system. Contractors may include, but are not limited to: Research centers, clinics, hospitals, universities, medical schools, research institutions/foundations, national associations, commercial organizations, collaborating State and Federal Government agencies, and coordinating centers. A current list of sites, including the address of any Federal Records Center where records from this system may be stored, is available by writing to the appropriate Coordinator listed under Notification Procedure.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM: Adults and/or children who are the subjects of clinical, epidemiologic, and biometric research studies of the NIH. Individuals with disease. Individuals who are representative of the general population or of special groups including, but not limited to: Normal controls, normal volunteers, family members and relatives; providers of services (e.g., health care and social work); health care professionals and educators, and demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to real and/or hypothesized risks (e.g., exposure to biohazardous microbial agents).

CATEGORIES OF RECORDS IN THE SYSTEM: The system contains data about individuals as relevant to a particular research study. Examples include, but are not limited to: Name, study identification number, address, relevant telephone numbers, Social Security Number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curriculum vitae); and associated correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM: ``Research and Investigation,'' ``Appointment and Authority of the Directors of the National Research Institutes,'' ``National Cancer Institute,'' ``National Eye Institute,'' ``National Heart, Lung and Blood Institute,'' ``National Institute on Aging,'' ``National Institute on Alcohol Abuse and Alcoholism,'' ``National Institute on Allergy and Infectious Diseases,'' ``National Institute of Arthritis and Musculoskeletal and Skin Diseases,'' ``National Institute of Child Health and Human Development,'' ``National Institute on Deafness and Other Communication Disorders,'' ``National Institute of Dental Research,'' ``National Institute of Diabetes, and Digestive and Kidney Diseases,'' ``National Institute of Drug Abuse,'' ``National Institute of Environmental Health Sciences,'' ``National Institute of Mental Health,'' ``National Institute of Neurological Disorders and Stroke,'' and the ``National Center for Human Genome Research,'' of the Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.)

PURPOSE(S) To document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a property identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

4. Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social Security numbers, date of birth and other identifiers may be disclosed: (1) To the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social Security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.

6. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in epidemiologic studies.

7. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices. (b). PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

8. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

9. Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.

10. The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.

11. Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE: Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and videotapes. For certain studies, factual data with study code numbers are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper/computer files.

RETRIEVABILITY: During data collection stages and follow-up, retrieval is by personal identifier (e.g., name, Social Security Number, medical record or study identification number, etc.). During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

SAFEGUARDS:

1. Authorized Users: Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager. Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual.
2. Physical Safeguards: Records are either stored in locked rooms during off-duty hours, locked file cabinets, and/or secured computer facilities. For certain studies, personal identifiers and link files

are separated and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.

3. Procedural Safeguards: Collection and maintenance of data is consistent with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When anonymous data is provided to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts for survey and research activities related to this system. The OHS project directors, contract officers, and project officers oversee compliance with these requirements. Personnel having access are trained in Privacy Act requirements. Depending upon the sensitivity of the information in the record, additional safeguard measures may be employed.

4. Implementation Guidelines: DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the HHS General Administration Manual and Part 6, ``ADP System Security'' of the HHS ADP Systems Security Manual. RETENTION AND DISPOSAL: Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1--``Keeping and Destroying Records'' (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Collaborative Perinatal Project records are retained in accordance with item 3000-G-4, which does not allow records to be destroyed. William A. White Clinical Research Program medical records (Saint Elizabeths Hospital, NIMH) are retained for 5 years after last discharge or upon death of a patient and then transferred to the Washington National Records Center, where they are retained until 30 years after discharge or death. Refer to the NIH Manual Chapter for specific conditions on disposal or retention instructions. SYSTEM MANAGER(S) AND ADDRESS: See Appendix I for a listing of current system managers. This system is for use by all NIH Institutes, Centers, and Divisions. The following system notices have been subsumed under this umbrella system notice.
09-25-0001 Clinical Research: Patient Records, HHS/NIH/NHLBI
09-25-0010Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI
09-25-0015 Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINDS
09-25-0016 Clinical Research: Collaborative Perinatal Project, HHS/ NIH/NINDS
09-25-0026 Clinical Research: Nervous System Studies, HHS/NIH/NINDS
09-25-0028 Clinical Research: Patient Medical Histories, HHS/NIH/ NINDS and HHS/NIH/NIDCD 09-25-0031 Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS
09-25-0037Clinical Research: The Baltimore Longitudinal Study of Aging, HHS/NIH/NIA
09-25-0038Clinical Research: Patient Data, HHS/NIH/NIDDK
09-25-0039 Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK
09-25-0040 Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK
09-25-0042 Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR
09-25-0044 Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR
09-25-0046 Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID
09-25-0053 Clinical Research: Vision Studies, HHS/NIH/NEI
09-25-0057 Clinical Research: Burkitt's Lymphonma Registry, HHS/ NIH/NCI
09-25-0060 Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI
09-25-0067 Clinical Research: National Cancer Incidence Surveys, HHS/NIH/NCI
09-25-0069 NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI

09-25-0074 Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI
09-25-0077 Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI
09-25-0126 Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI
09-25-0128 Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS
09-25-0129 Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/ NIDCD
09-25-0130 Clinical Research: Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI
09-25-0134 Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences, HHS/NIH/NIEHS
09-25-0142 Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA
09-25-0143 Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID
09-25-0145 Clinical Trials and Epidemiological Studies Dealing with Visual Disease and Disorders in the National Eye Institute, HHS/NIH/ NEI
09-25-0148 Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD
09-25-0152 Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR
09-25-0153 Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/ NIH/NICHD
09-25-0154 Biomedical Research: Records of Subjects: 1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/ NCI; and 2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD
09-25-0170 Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK
09-25-0172 Clinical Research: National Center for Human Genome Research, HHS/NIH/NCHGR
09-25-0201 Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH
09-25-0205 Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/ NIMH
09-25-0212 Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH

NOTIFICATION PROCEDURE: To determine if a record exists, write to the appropriate ICD Privacy Act Coordinator listed below. In cases where the requestor knows specifically which System Manager to contact, he or she may contact the System Manager directly (See Appendix I). Notification requests should include: Individual's name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and in specific cases, a notarized statement (some highly sensitive systems require two witnesses attesting to the individual's identity). A requestor must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the requestor is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.
Individuals will be granted direct access to their medical records unless the System Manager determines that such access is likely to have an adverse effect (i.e., could cause harm) on the individual. In such cases when the System Manager has determined that the nature of the record information requires medical interpretation, the subject of the record shall be requested to

designate, in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. The representative may be a physician, other health professional, or other responsible individual. In this case, the medical/dental record will be sent to the designated representative. Individuals will be informed in writing if the record is sent to the representative. This same procedure will apply in cases where a parent or guardian requests notification of, or access to, a child's or incompetent person's medical record. The parent or guardian must also verify (provide adequate documentation) their relationship to the child or incompetent person as well as his or her own identity to prove their relationship. If the requester does not know which Institute, Center or Division Privacy Act Coordinator to contact for notification purposes, he or she may contact directly the NIH Privacy Act Officer at the following address:

NIH Privacy Act Officer, Office of Management Assessment, Building 31, Room 1B05 31 Center Drive MSC 2075 Bethesda, MD 20892-2075. NIH Privacy Act Coordinators Office of the Director, (OD), NIH Associate Director for Disease Prevention, OD, NIH, Building 1, Room 260, 1 Center Drive Bethesda, MD 20892 National Cancer Institute (NCI)Privacy Act Coordinator, NCI, NIH Building 31, Room 10A34 31 Center Drive Bethesda, MD 20892 National Eye Institute (NEI) Privacy Act Coordinator, NEI, NIH Building 31, Room 6A-19 31 Center Drive Bethesda, MD 20892	National Heart, Lung and Blood Institute (NHLBI) Privacy Act Coordinator, NHLBI, NIH Building 31, Room 5A08 31 Center Drive Bethesda, MD 20892 National Institute of Allergy and Infectious Diseases (NIAID) Privacy Act Coordinator, NIAID, NIH Solar Building, Room 3C-23 6003 Executive Blvd. Bethesda, MD 20892 National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) Privacy Act Coordinator, NIAMS, NIH Natcher Building, Room 5QS49 45 Center Drive Bethesda, MD 20892 National Institute of Child Health and Human Development (NICHD) Privacy Act Coordinator, NICHD, NIH	6100 Executive Blvd., Room 5D01 North Bethesda, MD 20892 National Institute on Deafness and Other Communication Disorders NIDCD) Privacy Act Coordinator, NIDCD, NIH Building 31, Room 3C02 9000 Rockville Pike Bethesda, MD 20892 National Institute of Dental Research (NIDR) Privacy Act Coordinator, NIDR, NIH Building 31, Room 2C-35 31 Center Drive, MSC 2290 Bethesda, MD 20892-2290 National Institute of Diabetes and Digestive and Kidney Disease NIDDK) Privacy Act Coordinator, NIDDK, NIH Building 31, Room 9A47 31 Center Drive Bethesda, MD 20892
National Institute on Drug Abuse (NIDA) Privacy Act Coordinator, NIDA, NIH Parklawn Building, Room 10A_42 5600 Fishers Lane Rockville, Maryland 20857 National Institute of Environmental Health Sciences (NIEHS) Chief, Epidemiology Branch, NIEHS, NIH P.O. Box 12233 Research Triangle Park North Carolina 27709	National Institute of Mental Health (NIMH) Privacy Act Coordinator, NIMH, NIH Parklawn Building, Room 7C-22 5600 Fishers Lane Rockville, Maryland 20857 National Institute of Neurological Disorders and Stroke (NINDS) Privacy Act Coordinator, NINDS, NIH Federal Building, Room 816 7550 Wisconsin Avenue Bethesda, MD 20892	National Center for Human Genome Research (NCHGR) Chief, Office of Human Genome Communications NGHGR, NIH Building 38A, Room 617 9000 Rockville Pike Bethesda, Maryland 20892

RECORD ACCESS PROCEDURE:
Same as notification procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURE:
Contact the appropriate official at the address specified under Notification Procedure, and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES: The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: Referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological specimens; relatives; guardians; schools; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT: None.

Appendix I: System Managers and Addresses

Office of the Director, NIH Associate Director for Disease Prevention, OD, NIH Building 1, Room 260 1 Center Drive Bethesda, MD 20892	Chief, Genetic Epidemiology Branch, EBP, DCE, NCI, NIH Executive Plaza North, Suite 439 6130 Executive Blvd. Bethesda, MD 20892	Chief, Environmental Epidemiology Branch, DCE, NCI, NIH Executive Plaza North, Room 443 6130 Executive Blvd. Bethesda, MD 20892
National Cancer Institute Computer Systems Analyst, DCBD, NCI, NIH Executive Plaza North, Room 344 Bethesda, MD 20892	Chief, Clinical Genetics Section Clinical Epidemiology Branch, DCE, NCI, NIH Executive Plaza North, Suite 400 6130 Executive Blvd. Bethesda, MD 20892	Associate Director, Surveillance Program, DCPC, NCI, NIH Executive Plaza North, Room 343K 6130 Executive Blvd. Bethesda, MD 20892
American Burkitt's Lymphoma Registry Division of Cancer Etiology, NCI, NIH Executive Plaza North, Suite 434 6130 Executive Blvd. Bethesda, MD 20892	Program Director, Research Resources Biological Carcinogenesis Branch, DCE, NCI, NIH Executive Plaza North, Room 540 6130 Executive Blvd. Bethesda, MD 20892	Head, Biostatistics and Data Management Section, DCT, NCI, NIH 8601 Old Georgetown Road Bethesda, MD 20892
Chief, Clinical Research Branch Biological Response Modifiers Program Frederick Cancer Research and Development Center, DCT, NCI, NIH 501 W. 7th Street, Suite #3 Frederick, MD 21701	National Institute on Aging Computer Scientist, Longitudinal Studies Branch, IRP, NIH Gerontology Research Center, GRC 4940 Eastern Avenue Baltimore, MD 21224	10, Room 9S205 10 Center Drive Bethesda, MD 20892 National Institute of Child Health and Human Development Chief, Contracts Management Branch, NICHD, NIH Executive Plaza North, Room 7A07 6100 Executive Blvd. North Bethesda, MD 20892
Deputy Branch Chief, Navy Hospital NCI--Naval Medical Oncology Branch, DCT, NCI, NIH Building 8, Room 5101 Bethesda, MD 20814	Associate Director, Epidemiology, Demography and Biometry Program, NIA, NIH Gateway Building, Suite 3C309 7201 Wisconsin Avenue Bethesda, MD 20892	National Institute on Deafness and Other Communication Disorders Acting Director of Intramural Research, NIDCD, NIH Building 31, Room 3C02
Chief, Pharmaceutical Management Branch Cancer Therapy Evaluation	National Institute on Alcohol Abuse and Alcoholism Deputy Director, Division of	

Program, DCT, NCI, NIH Executive Plaza North, Suite 804 Bethesda, MD 20892 Director, Extramural Clinical Studies, BRB, BRMP, DCT, NCI, NIH Frederick Cancer Research and Development Center Fort Detrick Frederick, MD 21701 National Eye Institute Clinical Director, NEI, NIH Building 10, Room 10N_202 10 Center Drive Bethesda, MD 20892 Director, Division of Biometry and Epidemiology, NEI, NIH Building 31, Room 6A-52 31 Center Drive Bethesda, MD 20892 National Heart Lung and Blood Institute Administrative Officer, Division of Intramural Research, NHLBI, NIH Building 10 Room 7N220 10 Center Drive, MSC 1670 Bethesda, MD 20892-1670 Senior Scientific Advisor, OD Division of Epidemiology and Clinical Applications, NHLBI, NIH Federal Building, 220 7550 Wisconsin Avenue Bethesda, MD 20892	Biometry and Epidemiology, NIAAA, NIH Willco Building, Suite 514 6000 Executive Blvd., MSC 7003 Bethesda, MD 20892-7003 Deputy Director, Div. of Clinical and Prevention Res., NIAAA, NIH Willco Building, Suite 505 6000 Executive Blvd., MSC 7003 Bethesda, MD 20892-7003 National Institute of Allergy and Infectious Diseases Chief, Respiratory Viruses Section, LID, NIAID, NIH Building 7, Room 106 9000 Rockville Pike Bethesda, MD 20892 Chief, Hepatitis Virus Section, LID, NIAID, NIH Building 7, Room 202 9000 Rockville Pike Bethesda, MD 20892 Chief, Epidemology and Biometry Branch, DMID, NIAID, NIH Solar Building, Room 3A24 Bethesda, Maryland 20892 Special Assistant, Clinical Research Program, DAIDS, NIAID, NIH Solar Building, Room 2C-20 6003 Executive Blvd. Bethesda, MD 20892 National Institute of Arthritis and Musculoskeletal and Skin Diseases Clinical Director, NIAMS, NIH Building	31 Center Drive Bethesda, MD 20892 Director, Division of Human Communication, NIDCD, NIH Executive Plaza South, Room 400B 6120 Executive Boulevard Rockville, MD 20852 National Institute of Dental Research Deputy Clinical Director, NIDR, NIH Building 10, Room 1N-113 0 Center Drive, MSC 1190 Bethesda, MD 20892-1190 Research Psychologist, Clinical Invsetigations, NIDR, NIH Building 10, Room 1N114 10 Center Drive, MSC 1190 Bethesda, MD 20892-1190 Chief, Contract Management Section Extramural Program, NIDR, NIH Natcher Building, Room 4AN-44B 45 Center Drive, MSC 6402 Bethesda, MD 20892-6402 National Institute of Diabetes and Digestive and Kidney Diseases Chief, Clinical Investigations, NIDDK, NIH Building 10, Room 9N222 10 Center Drive Bethesda, MD 20892
Chief, Phoenix Clinical Research Section, NIDDK, NIH Phoenix Area Indian Hospital, Room 541 4212 North 16th Street Phoenix, Arizona 85016 Chief, Diabetes Research Section, DPB, DDEMD, NIDDK, NIH Natcher Building, Room 5AN-18G 45 Center Drive, MSC 6600 Bethesda, MD 20892 National Institute on Drug Abuse Privacy Act Coordinator, NIDA, NIH	Clinical Director, Neuroscience Research Center, DIRP, NIMH Saint Elizabeths Hospital, William A. White Building, Room 133 700 Martin Luther King Jr., Avenue, SE Washington, DC 20032 National Institute of Neurological Disorders and Stroke Chief, Epilepsy Branch, NINDS, NIH Federal Building, Room 114 7750 Wisconsin Avenue Bethesda, MD 20892	Director, Division of Fundamental Neurosciences, NINDS, NIH Federal Building, Room 916 7550 Wisconsin Ave Bethesda, MD 20892 Director, Division of Convulsive, Developmental and Neuromuscular Disorders, NINDS, NIH Federal Building, Room 816 7550 Wisconsin Avenue Bethesda, MD 20892 Director, Division of Demyelinating Atrophic, and Dementing Disorders, NINDS, NIH

Parklawn Building, Room 10A_42 5600 Fishers Lane Rockville, Maryland 20857 National Institute of Environmental Health Sciences Chief, Epidemiology Branch, NIEHS, NIH P.O. Box 12233 Research Triangle Park North Carolina 27709 National Institute of Mental Health Director, Intramural Research Program, NIMH, NIH Building 10, Room 4N-224 9000 Rockville Pike Bethesda, MD 20205 Privacy Act Coordinator, NIMH, NIH Parklawn Building, Room 7C22 5600 Fishers Lane Rockville, Maryland 20857	Chief, Development Neurology Branch, NINDS, NIH Federal Building, NIH 7550 Wisconsin Avenue Bethesda, MD 20892 Assistant Director, CNP, DIR, NINDS, NIH Building 10, Room 5N226 10 Center Drive Bethesda, MD 20892 Deputy Chief, Laboratory of Central Nervous Systems Studies Intramural Research Program, NINDS, NIH Building 36, Room 5B21, 9000 Rockville Pike Bethesda, MD 20892	Federal Building, Room 810 7550 Wisconsin Avenue Bethesda, MD 20892 Director, Division of Stroke and Trauma, NINDS, NIH Federal Building, Room 8A08 7550 Wisconsin Avenue Bethesda, MD 20892 National Center for Human Genome Research Chief, Office of Human Genome Communications, NCHGR, NIH Building 38A, Room 617 9000 Rockville Pike Bethesda, MD 20892